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No. 89-12

IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

CARITA RICHARDSON, BY S. & E. RICHARDSON, GUARDIANS, et al.
Petitioners,

v.

RICHARDSON-MERRELL, INC.
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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QUESTIONS PRESENTED

1. Where the highest court of the local court system has specifically held certain evidence sufficient to support a jury verdict, may a federal court in a subsequent diversity case controlled by *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), hold that *that same evidence* is insufficient to go to the jury? Does not the "outcome" test of the *Erie* progeny, particularly *Guaranty Trust Co. of New York v. York*, 326 U.S. 99 (1945), preclude that different result?

2. May Rule 703 of the Federal Rules of Evidence (which permits the use of expert testimony, based on facts or data not admissible in evidence, if "of a type reasonably relied upon by experts in the particular field") be used as a bludgeon by a trial court to deny a jury determination by ignoring evidence presented by eight experts who testify for a plaintiff (and defendant's experts agree) that the evidence is of the type reasonably relied upon by experts in the particular scientific field? Does the Court's refusal to consider this evidence after a jury verdict for the plaintiff violate the Seventh Amendment right to trial by jury, particularly after another Circuit (the 6th Circuit) has held that the issue was one for jury determination?

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CARITA RICHARDSON, BY S. & E. RICHARDSON, GUARDIANS, et al.
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RICHARDSON-MERRELL, INC.
Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Carita Richardson, et al., petitioners, respectfully pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINION BELOW

The opinion of the Court of Appeals is reported at 857 F.2d 823. It is reprinted in Appendix A herein, pp. A-1–A-22.

JURISDICTION

The decision of the Court of Appeals was issued on September 27, 1988. A timely petition for rehearing and suggestion for rehearing en banc was denied on April 6,

1989. The jurisdiction of this Court to review the decision below is invoked pursuant to 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISION AND RULE INVOLVED

7TH AMENDMENT TO THE CONSTITUTION

In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any court of the United States, than according to the rules of the common law.

FEDERAL RULES OF EVIDENCE

Rule 703. Bases of Opinion Testimony By Experts

The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

STATEMENT OF THE CASE

This is the case of Carita Richardson, the infant plaintiff, who was born with numerous severe birth deformities on February 16, 1976. Her mother while pregnant had taken the drug Bendectin, which was prescribed for "morning sickness" often suffered by pregnant women. Bendectin was manufactured by the defendant, Richardson Merrell, Inc., and it was the theory of plaintiffs' case that Carita Richardson's birth deformities had been caused by Bendectin. The case was originally filed in the

Superior Court of the District of Columbia and was removed to the federal district court on the basis of diversity of citizenship.

There was a jury trial lasting some eight weeks, during which both sides presented numerous experts. Plaintiffs presented eight experts (including Dr. Alan K. Done), all of whom testified to causation resulting from the ingestion of Bendectin. The jury returned a verdict for plaintiffs, but the District Judge overturned it and ordered judgment N.O.V. (and, in the alternative, a new trial) for the defendant. The Court of Appeals affirmed the judgment N.O.V. for the defendant (857 F.2d 823, pp. A-1–A-22, infra), on the basis of the reasoning of the District Judge, set forth in his decision reported in 649 F.Supp. 799 (1986).

Surprisingly, the Court of Appeals did not apply to this situation the well-known and already oft-repeated standard of its own prior decision, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535 (1984), that "the case was thus a classic battle of the experts, a battle in which the jury must decide the victor." Instead, the Court (following the lead of the District Judge) held that there was no "battle of the experts" because plaintiffs' eight experts had—in effect—been made to disappear by the testimony of one of defendant's experts, Dr. Raymond Seltser, who gave his opinion that the scientific literature failed to demonstrate that Bendectin caused birth defects (857 F.2d at 826, p. A-7).

The Court's opinion deals entirely with the testimony of one of plaintiffs' scientific experts, Dr. Alan K. Done, as constituting plaintiffs' case. The only reference of the Court of Appeals to the fact that plaintiffs presented seven other experts, in addition to Dr. Done, occurs in its footnote 38, 857 F.2d at 829, p. A-13, in which the Court says: "Our treatment of Dr. Done's testimony subsumes that of the other experts presented on Richardsons' behalf."

The Court of Appeals, in holding that plaintiffs had not presented evidence sufficient to go to a jury, summed it up this way (857 F.2d at 833, p. A-22):

> . . . the District Judge's grant of judgment N.O.V. in this case did not usurp the jury's function. Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been carried, are issues of law falling within the province of the court.

The Court of Appeals brushed off in a footnote the startling fact that *this very issue* of Bendectin causation had just recently been decided by the highest court of the District of Columbia which, on the same evidence as was presented here, reached a contrary conclusion. In *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100, decided in March of 1986, the District of Columbia Court of Appeals reversed a judgment N.O.V. for this same defendant (there was a name change) and reinstated the jury verdict for plaintiffs, on an analysis that was in conflict with that of the District Judge here and the Circuit Court. The D.C. Court of Appeals in *Oxendine* specifically recognized and adopted a theory of the effect of plaintiffs' evidence that contradicted the theory adopted by the two federal courts.

It was not that the District Judge claimed there was any difference in the evidence presented in the two cases. He specifically said, at the beginning of his decision (649 F.Supp. at 799), issued in December of 1986: "This trial was a virtual reprise of *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986), . . ." And immediately thereafter, referring to the fact that the trial judge in *Oxendine* had set aside a jury verdict for plaintiffs, the District Judge said: "This Court, having heard *substantially the same evidence* as the trial judge in *Oxendine*, is of the same opinion as to its efficacy." (Emphasis added).

Although this was a diversity-of-citizenship case controlled by *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938), the District Judge made no mention of the *Erie* doctrine and whether he might not be bound by the "outcome" effect of the local court's decision in *Oxendine*. He simply announced his disagreement with the highest court of the District of Columbia, although he acknowledged (649 F.Supp. at 799) that its *Oxendine* decision "accurately summariz[ed] the testimony."

He refused to accept that decision, stating instead that he agreed with the decision (of the trial judge) that had been reversed.

The Circuit Court did mention the *Erie* doctrine, but just barely. In footnote 9 of its opinion, 857 F.2d at 825, p. A-4–6, the Circuit Court said that plaintiffs' "*Erie* challenge must be rejected," giving several reasons. Its first reason was that plaintiffs' argument "ignores the differences in the evidence presented in the two cases." (This is, as has been said, directly contrary to the statement of the District Judge that there were essentially no differences.) The next reason given by the Circuit Court was that "the *Erie* doctrine applies to state *substantive*, not *procedural*, law to be followed by federal courts exercising diversity jurisdiction." And finally, the Circuit Court said: "In addition, it is clear that *Erie* does not affect the federal courts' application of the Federal Rules of Evidence. . . . Because the admissibility of evidence, which is governed by the Federal Rules of Evidence, is the crux of our decision in this case, . . . the Richardsons' argument must be rejected."

This diversity case thus suffered a different outcome in the federal court system than would have been the case in the local court system—a cruel irony, when we consider that this *Richardson* case actually was originally filed in the Superior Court of the District of Columbia, where it would have been unquestionably controlled by *Oxendine*, and was removed to the federal district court.

REASONS FOR GRANTING THE WRIT

1. The Erie Railroad Issue

The fundamental principle of *Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938),[1] is that in cases (such as this diversity case) involving state law, the outcome of the suit "in a federal court instead of in a state court a block away, should not lead to a substantially different result." *Guaranty Trust Co. of New York v. York*, 326 U.S. 99, 109 (1945). Indeed, "a federal court adjudicating a state-created right solely because of the diversity of citizenship of the parties is for that purpose, in effect, only another court of the State." *Id.* at 108.

Yet here, the local court system had (prior to the District Court's decision) ruled upon virtually this same case, with a totally different result. The District Judge acknowledged that fact; he said: "This case is a virtual reprise of *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (D.C. 1986)," and he said he had heard, in this case, "substantially the same evidence as the trial judge in *Oxendine*." *Richardson v. Richardson-Merrell, Inc.*, 649 F.Supp. 799 (D.D.C. 1986). But, he complained, the District of Columbia Court of Appeals reversed the trial judge's grant of judgment N.O.V. "in an opinion which, although accurately summarizing the testimony, did not address the significance of certain evidence bearing upon the current state of scientific knowledge." *Id.* at 799. He paid no deference at all to the decision of the highest court of the District of Columbia and proceeded to hold to the contrary.

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[1] *Erie Railroad* is applicable in the federal courts of the District of Columbia. See *Anchorage-Hynning & Co. v. Moringiello*, 697 F.2d 356 (D.C. Cir. 1983); *Steorts v. American Airlines, Inc.*, 647 F.2d 194 (D.C. Cir. 1981).

The Court of Appeals at least recognized the existence of an *Erie Railroad* factor but held that *Erie* did not apply. See 857 F.2d at 825 (p. A-4), note 9. It gave three reasons. Its first reason was that there are "differences in the evidence presented in the two cases." This is not tenable; the District Judge, who heard the evidence, said that it was "substantially the same evidence."

The Court's second reason was that "the *Erie* doctrine applies to state *substantive*, not *procedural*, law. . . ." By inference, we gather that the Court is saying that what we have here is "procedural" law. It is true that as a kind of shorthand, we talk about *Erie* as applying only to "substance" as against "procedure," but as this Court said in *Hanna v. Plumer*, 380 U.S. 460, 469(1965): "The line between 'substance' and 'procedure' shifts as the legal context changes." And the Court then quoted from *Guaranty Trust Co. of New York v. York*, supra, 326 U.S. at 108: "Each implies different variables depending upon the particular problem for which it is used." Here, the treatment of the evidence by the Circuit Court of Appeals was *substantively* in conflict with that of the District of Columbia Court of Appeals. The crux of the *Erie* problem here is this ruling of the Court below (857 F.2d at 830, p. A-16):

> These three types of studies then—chemical, *in vitro*, and *in vivo*—cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. *Studies of this kind, singly or in combination, are not capable of providing causation* in human beings in the face of the overwhelming body of contradictory epidemiological evidence. (Emphasis added)

This is precisely to the contrary of what the highest court of the local court system held *on this very issue, and on the same evidence*. In the *Oxendine* case, the D.C. Court of Appeals held (506 A.2d at 1110):

> In ruling on a motion for judgment N.O.V., the court must view the evidence as a whole, not in fragments. Like the pieces of a mosaic, the individual studies showed little or nothing when viewed separately from one another, but they combined to produce a whole that was greater than the sum of its parts: a foundation for Dr. Done's opinion that Bendectin caused appellant's birth defects.

The D.C. Court of Appeals went on to say, with regard to Dr. Done:

> The evidence also established that Dr. Done's methodology was generally accepted in the field of teratology, and his qualifications as an expert have not been challenged. Because he fully explained to the jury that his opinion was based on *all* of the studies, we cannot say that no reasonable juror could reach a verdict in favor of appellant.

We have then a square conflict on the sufficiency of the evidence to support a jury verdict. *The case turned on this difference,* and came out with a different result in the federal court. By whatever label we choose to attach, this is an *Erie Railroad* issue. The *Oxendine* decision articulated the local law of the District of Columbia.

We pause to say what this issue is *not*. This is not a case in which there is a federal "affirmative countervailing consideration" such as whether or not to afford trial by jury, as in *Byrd v. Blue Ridge Rural Electric Corp., Inc.*, 356 U.S. 525 (1958). This is not a case of a conflict of the *Erie* doctrine with the Federal Rules of Civil Procedure, as in *Hanna v. Plumer,* supra. This is not a case involving whether the sufficiency of evidence is to be tested by a "federal" standard or a "state" standard—see, e.g., *Dick v. New York Life Ins. Co.*, 359 U.S. 437, 444-5 (1959). This

case is controlled by *Stoner v. New York Life Ins. Co.* 311 U.S. 464 (1940), which held specifically that (in a case in which the factual issue was whether the insured was disabled within the meaning of the insurance policy) it was error for the federal court to refuse to follow the ruling of a state court which had held that, as to the same insured and the same insurance policy, the evidence *was* sufficient to create a jury issue as to the fact of disability.

No one has suggested that the *standard* in the local court system of the District of Columbia is different from the standard applied in federal courts. This is simply a case involving the outcome of the case, where that outcome in a state court is already known.

This Court should grant certiorari in order to make clear the effect of *Erie Railroad* where a state court has determined a case on the same evidence as is subsequently adduced in a federal diversity case in that state.

2. The Rule 703 and Trial By Jury Issue

> If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion. . . . If there are any circumstances which permit an exception, they do not now occur to us. *West Virginia State Board of Education v. Barnette*, 319 U.S. 624, 642 (1943).

Rule 703 of the Federal Rules of Evidence was invoked here as a bludgeon by the Court below to justify its action which deprived plaintiffs of trial by jury. That was a misuse of the Rule. On the contrary, that Rule which (as the Court below admitted) "was intended to broaden the ac-

ceptable bases of expert opinion,"[2] reads as follows:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, *the fact or data need not be admissible in evidence*. (Emphasis added)[3]

The eight experts who testified on behalf of plaintiffs all testified that the evidence they presented was of the type generally and reasonably relied upon by experts in the particular field in forming opinions on the subject, and thus within Rule 703. And defendants' experts agreed with this! But the Court below held that it is the judge, and not the jury, who is empowered to pass upon whether or not expert opinions so qualified. These questions, said the Court, "are matters of law for the court to decide." 857 F.2d at 829, p. A-13, infra.

This is directly contrary to what other circuits have held. Both the Fifth Circuit and the Third Circuit have held that in determining under Rule 703 whether an expert's opinion is "of a type reasonably relied upon by experts in the particular field" the trial court "should defer to the expert's opinion of what data they [sic] find reasonably reliable." *Peteet v. Dow Chemical Co.*, 868 F.2d 1428, 1432 (5th Cir. 1989), citing *Greenwood Utils. Comm'n v. Mississippi Power Co.*, 751 F.2d 1484, 1485 (5th Cir. 1985), and *In re Japanese Elec. Prods. Antitrust Litig.*, 723 F.2d 238, 277 (3rd Cir. 1983), rev'd on other grounds, 475 U.S. 574 (1986).

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[2]*Merit Motors, Inc. v. Chrylser Corp.*, 569 F.2d 666, 673 (D.C. Cir. 1977), quoted by the Court below, 857 F.2d at 829, p. A-14.

[3]The emphasized provision, which relieved litigants of the necessity of showing admissibility in evidence, was "the most controversial" aspect of Rule 703 (and possibly of the Rules as a whole). 11 *Moore's Federal Practice* (1989) p. VII-49.

The Court below said that the question of Bendectin's alleged effects "is scientific in nature, and it is to the scientific community that the law must look for the answer." 857 F.2d at 829, p. A-12. The Court then proceeded to hold that the opinion of one of plaintiffs' scientific witnesses "lacks an adequate basis" (and the Court threw in, for good measure, the opinions of plaintiffs' seven other experts) because it is a profoundly minority view. But this is contrary to the holding of the Fifth Circuit in *Osburn v. Anchor Laboratories, Inc.*, 825 F.2d 908, 915 (1987), that

> An expert's opinion need not be generally accepted in the scientific community before it can be sufficiently reliable and probative to support a jury finding. . . . What is necessary is that the expert arrived at his causation opinion by relying on *methods* that other experts in his field would reasonably rely on in forming their own, possibly different opinions, about what caused the patient's disease.

The Third Circuit, in the *Japanese Electronic Products Litigation* case, supra, articulated the proper approach. There, the District Judge, using his own criteria, excluded expert testimony precisely on the ground that it was not "of a type reasonably relied upon by experts in the particular field in forming opinions." The Court of Appeals reversed, saying (723 F.2d at 276):

> The proper inquiry is not what the court deems reliable, but what experts in the proper discipline deem it to be . . .

Thus, said the Third Circuit (p. 277), the District Court was in error insofar as it "substituted its own views of reasonable reliance for those of the experts."

There was no dispute, in the case at bar, as to the propriety of plaintiffs' *methodology.* Defendant's experts agreed that it was proper. Indeed, in Bendectin litigation itself, where this very issue was raised in the Sixth Circuit in *In Re: Bendectin Litigation,* 857 F.2d 290 (1988), the Sixth Circuit said:

> In reviewing the record, . . . as we observed earlier, the jury verdict following trial here might have been for the Plaintiffs instead of for the Defendant. (p. 325).
>
> * * * * * *
>
> It is important to observe that the jury, if it credited Dr. Swan's testimony, would plainly have understood that it could return a verdict for the Plaintiffs where Bendectin was one of the proximate causes of the defects. (p. 311, n.14)

We thus have a conflict of circuits on this most important issue—the sufficiency of scientific evidence in jury cases. In the Sixth Circuit (as in the D.C. Court of Appeals), a plaintiff creates a jury issue by presenting the testimony of qualified scientific experts on the question of Bendectin causation. But in the Circuit Court below, that same evidence is held to be insufficient.

In holding that the testimony of plaintiffs' experts did not rise scientifically to an acceptable level of admissible evidence, the Court below weighed the evidence. It thereby acted in direct violation of the historic mandate of this Court expressed recently in *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 255 (1986):

> *Credibility determinations, the weighing of the evidence,* and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict. (Emphasis added)

This statement summarizes the long-time holdings of this Court, see *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970), and the D.C. Circuit has often recognized it.[4] But the decision at bar, though purporting to follow those holdings, has invented a way around them, doing away with the right of trial by jury in the process. The Court held that the "question whether Bendectin causes limb reduction defects is scientific in nature, and it is to the scientific community that the law must look for the answer," 857 F.2d at 829, p. A-12, but then—in this jury case—the Court held that it is the function of the *judge*, not the jury, to decide that question.

Presumably this would have been the Circuit Court's position even if plaintiffs had produced not eight but one hundred or one thousand experts testifying that Bendectin is a teratogen and caused plaintiff's birth defects.[5] Under that Court's formulation of the principle involved, a judge could always foreclose a jury's consideration of what the "scientific community" had determined.

The correct principle was set forth by the Court below in its decision of only five years ago, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), cert. den. 469 U.S. 1062 (1984), when it said, p. 1534, that

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[4]See *Kozup v. Georgetown University*, 851 F.2d 437, 439 (D.C. Cir. 1988). Indeed, the Court below said, in this very case, 857 F.2d at 827: "The Court must consider all of the evidence offered by the parties, but *it should neither assess witness credibility nor weigh the evidence*." (Emphasis added)

[5]The Court below said, footnote 38, p. A-13, that "the number of experts presented does not in itself preclude a finding that there was insufficient evidence or automatically create an issue for the jury." Its treatment of Dr. Done's testimony, said the Court, "subsumes that of the other experts presented on Richardsons' behalf."

> judges . . . have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony.

The decision below has sent shivers across the country among members of the bar. It has thrown into doubt the continuing role of the jury in a case involving scientific controversy. Already another Court of Appeals has utilized the approach of the Court below to reverse a jury verdict and entry of judgment for plaintiffs in another Bendectin case, holding that the court could find insufficient the testimony of numerous qualified scientific experts that this drug caused plaintiff's birth defects. *Brock v. Merrell Dow Pharmaceuticals, Inc.*,—F.2d—(5th Cir. June 6, 1989).

CONCLUSION

This Court should grant certiorari to clarify the effect of *Erie Railroad v. Tompkins* and of the Seventh Amendment in cases such as this.

Respectfully submitted,

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APPENDIX

Notice: This opinion is subject to formal revision before publication in the Federal Reporter or U.S.App.D.C. Reports. Users are requested to notify the Clerk of any formal errors in order that corrections may be made before the bound volumes go to press.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 10, 1988 Decided September 27, 1988

Nos. 87-7023 and 87-7024

CARITA RICHARDSON, Infant, by S. & E. Richardson, Guardians, *et al.*, APPELLANTS

v.

RICHARDSON-MERRELL, INC., a Delaware Corporation, *et al.*

Appeal from the United States District Court for the District of Columbia

(Civil Action No. 83-03505)

Barry J. Nace, with whom *Thomas H. Tate*, *Lynn S. Spradley*, *Irving R. M. Panzer* and *Timothy D. Junkin* were on the brief, for appellants.

Mark L. Austrian, with whom *John B. Williams* and *Frederick D. Baker* were on the brief, for appellee.

Geoffrey R. W. Smith and *Bruce J. Brennan* were on the brief for Pharmaceutical Manufacturers Association, amicus curiae, urging affirmance.

Bills of costs must be filed within 14 days after entry of judgment. The court looks with disfavor upon motions to file bills of costs out of time.

Before ROBINSON, SILBERMAN and D. H. GINSBURG, *Circuit Judges.*

Opinion for the Court filed by *Circuit Judge* ROBINSON.

ROBINSON, *Circuit Judge*: Carita Richardson and her parents brought an action in the District Court alleging that her congential limb defects resulted from ingestion of Bendectin by her mother, Etheleen, during her pregnancy. At the time, Bendectin, an anti-nausient drug, was manufactured by Richardson-Merrell, Inc., which since has been succeeded by Merrell-Dow Pharmaceuticals, Inc. Following a lengthy trial, the jury returned a verdict awarding damages in the sums of $1 million to Carita and $160,000 to the parents. On Merrell's motion, the District Court granted judgment n.o.v. in its favor, and the propriety of doing so is the single question on this appeal. After careful consideration of the record, we agree that the evidence was so one-sided as to warrant fully the court's action. Accordingly, we affirm.

I. THE BACKGROUND

The Bendectin taken by Mrs. Richardson was a combination of pyridoxine hydrochloride (vitamin B-6), doxylamine succinate (an antihistamine), and dicyclomine hydrochloride (an antispasmodic).[1] In 1956, the drug was approved by the Federal Drug Administration (FDA) as safe for the treatment of nausea and vomiting during pregnancy. Between 1957, when Bendectin was initially marketed, and 1983, when Merrell discontinued marketing of the drug—apparently as the result of litigation—Bendectin was used by more than thirty million pregnant women. FDA approval has never been rescinded.

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[1] Dicyclomine hydrochloride was dropped from the formulation of Bendectin in 1976.

Early in her pregnancy,[2] Mrs. Richardson developed morning sickness, the nausea that pregnant women sometimes suffer. On her doctor's prescription, she began taking two Bendectin tablets at night and one in the morning. That she continued to do for at least the duration of the period of organogenesis—from about the 24th through the 56th day post-conception—the time during which Carita's limbs were forming in utero. Sadly, Carita was born with limb-reduction defects.[3]

A. *The Procedural History*

Carita and her parents filed suit in the District Court for the District of Columbia. Along with over 1,500 other Bendectin lawsuits, the case was transferred for pretrial proceedings, pursuant to an order of the Judicial Panel on Multidistrict Litigation, to the Southern District of Ohio,[4] where a jury trial was held on the common issue of causation for all plaintiffs who had not opted out.[5] Because the Richardsons elected not to participate in the common-issues trial, their case was retransferred to the District Court here.

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[2] Richardson, then age 38, had three other children, all of whom were born without birth defects.

[3] Carita's left arm was deformed, with an underdeveloped humerus fused to the radius at the elbow and terminating in a hand with only two digits. Her right arm was normal. The right and left femurs were underdeveloped. Her lower left leg was normal, but she had no lower right leg at all. An appendage resembling a foot was attached to her right hip, and later was amputated.

[4] *In re Richardson-Merrell, Inc. "Bendectin" Prods. Liab. Litig. (No. II)*, 533 F.Supp. 489 (J.P.M.D.L. 1982).

[5] The trial involved more than a thousand plaintiffs and resulted in a finding by the jury that Bendectin did not cause birth defects. *In re Richardson-Merrell, Inc. "Bendectin" Prods. Liab. Litig.*, 624 F.Supp. 1212 (S.D. Ohio 1985) (M.D.L. No. 486), *aff'd in part, vacated in part, and remanded with directions sub nom. In re Bendectin Litig.*, No. 85-3858 (6th Cir. Aug. 30, 1988), 857 F.2d 290.

At trial, to avoid a compromise verdict, the District Court submitted the case to the jury in two stages, first on the issue of causation and then on issues of failure to warn and damages. The jury found that Bendectin was a human teratogen, a substance capable of causing birth defects, when taken in recommended doses by a pregnant woman during the period of organogenesis of a unborn child and that Bendectin was the proximate cause of Carita's birth defects. The jury also found a lack of proper warning of the dangers associated with the drug, and accordingly, returned its $1.16 million verdict for the Richardsons.

Merrell moved for judgment n.o.v. or, in the alternative, for a new trial. The court granted the motion for judgment n.o.v., holding that on the basis of the evidence presented no reasonable jury could find that Carita's birth defects were more likely than not caused by Bendectin.[6] Alternatively, the court granted Merrell's motion for a new trial [7] on the ground that the verdict was "clearly contrary to the weight of the evidence." [8]

The Richardsons argue that the District Court erred in both respects because there was sufficient credible evidence to support the verdict in their favor.[9] Merrell con-

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[6] *Richardson* v. *Richardson-Merrell, Inc.*, 649 F. Supp. 799, 799 (D.D.C. 1986) [hereinafter *Richardson*].

[7] The court's action in this regard was in conformity with the procedure specified by Rule 50(c)(1) of the Federal Rules of Civil Procedure: "If the motion for judgment notwithstanding the verdict . . . is granted, the court shall also rule on the motion for a new trial, if any, by determining whether it should be granted if the judgment is thereafter vacated or reversed, and shall specify the grounds for granting or denying the motion for the new trial."

[8] *Richardson, supra* note 6, 649 F.Supp. at 799-800.

[9] The Richardsons also assert that because this is a diversity case, the District Court disregarded the teaching of *Erie R.R.* v. *Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188

tends that judgment n.o.v. was proper because the opinions of the Richardsons' experts were inadequate to demonstrate causation by a preponderance of the evidence.

(1938), by reaching a result different from that arrived at by the District of Columbia Court of Appeals in *Oxendine* v. *Merrell Dow Pharmaceuticals, Inc.*, 506 A.2d 1100 (1986), a Bendectin case in which substantially similar evidence was presented. There, as here, judgment n.o.v. had been granted following a jury verdict adverse to Merrell, but the Court of Appeals reversed on the ground that there was sufficient evidence to support the verdict.

In taking account of that decision, the District Court in this case concluded that although the *Oxendine* court summarized accurately the testimony presented, it "did not address the significance of certain evidence bearing upon the current state of scientific knowledge"—evidence elaborately presented in the case at bar. It was the District Court's view that the Court of Appeals in *Oxendine* had "judicially reopened an esoteric 20-year-old controversy which is by now essentially settled within the scientific community." *Richardson, supra* note 6, 649 F.Supp. at 799.

Subsequent to oral argument in the case at bar, the defendant in *Oxendine* moved for relief from the judgment, and retrial of the case was ordered. *Oxendine* v. *Merrell Dow Pharmaceuticals, Inc.*, Civ. No. 1245-82 (Super. Ct. D.C. Feb. 12, 1988) (memorandum order). An appeal from that ruling is now pending before the Court of Appeals, leaving unsettled the ultimate outcome in *Oxendine* and the decisional foundation thereof. But whatever the fate of *Oxendine* may be, the Richardsons' *Erie* challenge must be rejected. We note that the Richardsons' argument ignores the differences in the evidence presented in the two cases. Moreover, the *Erie* doctrine applies to state *substantive*, not *procedural*, law to be followed by federal courts exercising diversity jurisdiction. See, e.g., *Guaranty Trust Co.* v. *York*, 326 U.S. 99, 65 S.Ct. 1464, 89 L.Ed. 2079 (1945). In addition, it is clear that *Erie* does not affect the federal courts' application of the Federal Rules of Evidence. *Eli Lilly & Co.* v. *Home Ins. Co.*, 254 U.S. App.D.C. 1, 6, 794 F.2d 710, 715 (1986); see also C. Wright, A. Miller & E. Cooper, Federal Practice and Procedure § 4512 (1982). Because the admissibility of testimony, which is governed by the Federal Rules of Evidence, is the crux of our de-

After an exhaustive review of the trial transcript and the exhibits introduced by the parties, we conclude that judgment n.o.v. was appropriate.

B. *The District Court's Opinion*

In granting judgment n.o.v., the District Court stated:

> No reasonable jury could find on the basis [of the evidence presented] that this infant plaintiff's birth defects were more likely than not to have been caused by her intrauterine exposure to Bendectin; alternatively, even if such a finding were reasonable, it is nevertheless so clearly contrary to the weight of the evidence that the case must be retried.[10]

The court summarized the evidence, focusing on the testimony of Dr. Alan K. Done, the Richardson's principal witness on causation. On the basis of (1) Bendectin's chemical structure, (2) *in vitro* (test tube) studies, (3) *in vivo* (animal) teratology studies conducted by Merrill and others, and (4) the "human data" he had reviewed—epidemiological studies which he found "defective, inconclusive, or both" [11]—Dr. Done expressed the opinion that "to a 'reasonable degree of medical certainty,' Bendectin was not only 'capable' of causing birth defects in humans, but that it had, in fact, caused those limb defects with which Carita Richardson had been born." [12]

Despite this opinion, the court held that there was no "battle of experts" in this case, a circumstance which,

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cision in this case, see *infra* notes 37-42 and accompanying text, the Richardsons' argument must be rejected.

Appellants also challenge the District Court's alternative grant of a new trial. Our disposition, however, makes it unnecessary for us to reach this issue.

[10] *Richardson, supra* note 6, 649 F.Supp. at 799.

[11] *Id.* at 801. Epidemiology is the study of the frequency of disease in human populations and the way in which the frequency varies from one population to another.

[12] *Id.*

if true, would have required that the verdict remain standing.[13] The court apparently concluded that there was not an adequate foundation for Dr. Done's theory on Bendectin, a theory undermined by an overwhelming array of contrary opinion published in the scientific literature and presented by the defense.

The District Court also examined closely the testimony of Dr. Raymond Seltser, an expert witness for the defense, who testified about the significance of the scientific literature on Bendectin. Dr. Seltser's review of the literature uncovered fourteen cohort studies and seven case control studies, "in none of which is there to be found a statistically significant increase in the relative risk of any congential limb malformations associated with Bendectin exposure." [14] By the court's estimate, "the importance of [Dr. Seltser's] testimony lies in his presentation of the totality of the published scientific literature [on Bendectin], which collectively represents the sum of all that can be said to be scientifically 'known' of the matter at present." [15] The court added:

> Excepting their own empirical observations, the "literature" is to scientists both the ultimate authority as to and the most respected repository of scientific knowledge. And the literature on Bendectin, individually and in the aggregate, fails to demonstrate Bendectin's teratogenicity to a scientifically acceptable degree of accuracy.[16]

The District Court observed that Dr. Done had neither performed his own studies nor published his criticisms

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[13] *Id.* at 801-802; see *Ferebee* v. *Chevron Chem. Co.*, 237 U.S.App.D.C. 164, 170, 736 F.2d 1529, 1535 (1984) ("[t]he case was thus a classic battle of the experts, a battle in which the jury must decide the victor").

[14] *Richardson, supra* note 6, 649 F.Supp. at 802 n.9.

[15] *Id.* at 802.

[16] *Id.*

of the studies performed by others, but nonetheless testified in contradiction to "not only Dr. Seltser but to the findings of all those researchers who have studied and published in the twenty-odd years since the investigation of Bendectin began." [17]

The District Court also noted that Dr. Seltser's judgment regarding the current state of knowledge about Bendectin within the scientific community was corroborated by FDA's Fertility and Maternal Health Drugs Advisory Committee, which was convened in 1980 to evaluate the evidence on alleged Bendectin-related malformations.[18] After studying the literature and considering testimony presented during a two-day hearing, the Committee concluded that there was no increased incidence of birth defects among Bendectin-exposed infants; that there was no need for further animal or epidemiological studies; and that Bendectin should not be withdrawn from the market.[19] FDA adopted the findings of the Committee and has not since changed its position.[20]

The District Court concluded that in light of Bendectin research and the published literature, Dr. Done's opinion was beyond the range of acceptability. The court's summary of its analysis is succinct:

> Though Dr. Done might disagree, there is now nearly universal scientific consensus that Bendectin has not been shown to be a teratogen, and, the issue being a scientific one, reasonable jurors could not reject that consensus without indulging in precisely the same speculation and conjecture which the multiple investigations undertook, but failed, to confirm. That Dr. Done remains an unbeliever and was will-

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[17] *Id.*

[18] *Id.* at 802-803.

[19] *Id.*

[20] *Id.*

> ing to testify to his disbelief "with reasonable medical certainty" does not mandate that this case be left as the jury decided it. Wihout a genuine basis "in or out of the record," even his expert "theoretical speculations" are insufficient to sustain the plaintiff's burden of proving, by a preponderance of the evidence, that Bendectin not only causes congenital defects generally, but that, in particular, it caused those limb reduction defects with which Carita Richardson was most unfortunately born.[21]

As a result, the court granted Merrell's motion for judgment n.o.v.

II. Standard of Review

The standard for awarding judgment n.o.v. is the same as that governing rulings on motions for directed verdicts.[22] Judgment n.o.v. is proper only if, viewing the evidence in the light most favorable to the plaintiff and giving him the advantage of every fair and reasonable inference that the evidence may permit, there can be but one reasonable conclusion drawn.[23] "If fair-minded people may differ as to the conclusion, or if there is substantial conflicting evidence," we have said, "the judgment n.o.v. motion must be denied."[24] The court must

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[21] *Id.* at 803 (citing *Merit Motors, Inc.* v. *Chrysler Corp.*, 187 U.S.App.D.C. 11, 18, 569 F.2d 666, 673 (1977)).

[22] *Coburn* v. *Pan Am. World Airways*, 229 U.S.App.D.C. 61, 64, 711 F.2d 339, 342 (1983); *Vander Zee* v. *Karabatsos*, 191 U.S.App.D.C. 200, 203, 589 F.2d 723, 726 (1978).

[23] *Carter* v. *Duncan-Huggins, Ltd.*, 234 U.S.App.D.C. 126, 128, 727 F.2d 1225, 1227 (1984); *Coburn* v. *Pan Am. World Airways, supra* note 22, 229 U.S.App.D.C. at 64, 711 F.2d at 342; *Metrocare* v. *Washington Metro. Area Transit Auth.*, 220 U.S.App.D.C. 104, 106, 679 F.2d 922, 924 (1982); *Vander Zee* v. *Karabatsos, supra* note 22, 191 U.S.App.D.C. at 203, 589 F.2d at 726.

[24] *Carter* v. *Duncan-Huggins, Ltd., supra* note 23, 234 U.S. App.D.C. at 128, 727 F.2d at 1227.

consider all of the evidence offered by the parties, but it should neither assess witness credibility nor weigh the evidence.[25] On appeal, this court's review of the action taken on such a motion stress the same course as that binding on the District Court when it considered the motion beforehand.[26] "Because a motion for judgment n.o.v. intrudes upon the jury's domain, that question is very narrow." [27]

Recently, in *Anderson* v. *Liberty Lobby, Inc.*,[28] a summary judgment case, the Supreme Court clarified the standard for determining when it is appropriate to take a case from the jury.[29] *Anderson* was a libel action in

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[25] *Id.* at 128-129, 727 F.2d at 1227-1228.

[26] *Id.* at 128, 727 F.2d at 1227.

[27] *Id.* It is of no moment that the District Court granted judgment n.o.v. instead of taking the case from the jury earlier by directing a verdict for Merrell. We have frequently counseled that "the better practice in such situations is to let the case go to the jury and, if it finds liability, to set [the verdict] aside." *Law* v. *Virginia Stage Lines, Inc.*, 144 U.S. App.D.C. 115, 116-117, 444 F.2d 990, 991-992 (1971); see also *Peigh* v. *Baltimore & O. R.R.*, 92 U.S.App.D.C. 198, 202, 204 F.2d 391, 396 (1953) ("if there is room for a difference of opinion, the wise course is for the trial judge to allow the case to go to the jury. If a verdict is deemed by the court to be contrary to the evidence, judgment may be entered *non obstante veredicto*").

[28] 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

[29] The Court noted that the standard for direction of a verdict mirrors the standard for summary judgment, and that action in either instance is proper "if, under the governing law, there can be but one reasonable conclusion as to the verdict." *Id.* at 250, 106 S.Ct. at 2511, 91 L.Ed.2d at 213. The Court pointed out that " '[t]he primary difference between the two motions is procedural; summary judgment motions are usually made before trial and decided on documentary evidence, while directed verdict motions are made at trial and decided on the evidence that has been admitted,' " *id.* at 251, 106 S.Ct. at 2515, 91 L.Ed.2d at 214 (quoting *Bill Johnson's*

which the Court reversed this circuit's holding that the clear-and-convincing evidentiary standard need not be taken into consideration at the summary judgment stage. "[W]e are convinced," the Court explained, "that the inquiry involved in a ruling on a motion for summary judgment or for a directed verdict necessarily implicates the substantive evidentiary standard of proof that would apply at the trial on the merits." [30] In a run-of-the-mill civil case, the Court noted, "[t]he judge's inquiry . . . unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict." [31] Thus, the Court concluded that "the judge must view the evidence presented through the prism of the substantive evidentiary burden." [32]

The Court, citing long-established precedent, pointed out that a judge is not required to submit a case to the jury " 'merely because some evidence has been introduced by the party having the burden of proof, unless the evidence be of such a character that it would warrant the jury in finding a verdict in favor of that party.' " [33]

Restaurants, Inc. v. *NLRB*, 461 U.S. 731, 745 n.11, 103 S.Ct. 2162, 2171 n.11, 76 L.Ed.2d 277, 290 n.11 (1983)), but that "[i]n essence, though, the inquiry under each is the same: whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law," 477 U.S. at 251-252, 106 S.Ct. at 2515, 91 L.Ed.2d at 214. Because the identical standard governs a court's ruling on a motion for judgment n.o.v., *Coburn* v. *Pan Am. World Airways, supra* note 22, 229 U.S.App.D.C. at 64, 711 F.2d at 342; *Vander Zee* v. *Karabatsos, supra* note 22, 191 U.S.App.D.C. at 203, 589 F.2d at 726; see also *Lester* v. *Dunn*, 154 U.S.App.D.C. 399, 401, 475 F.2d 983, 985 (1973), the *Anderson* decision provides guidance in this case as well.

[30] 477 U.S. at 252, 106 S.Ct. at 2512, 91 L.Ed.2d at 214.

[31] *Id.*

[32] *Id.* at 254, 106 S.Ct. at 2513, 91 L.Ed.2d at 215.

[33] *Id.* at 251, 106 S.Ct. at 2511, 91 L.Ed.2d at 213 (quoting *Improvement Co.* v. *Munson*, 81 U.S. (14 Wall.) 442, 448, 20 L.Ed. 867, 872 (1872)).

"If the evidence is merely colorable, or is not significantly probative," the Court stated, "summary judgment may be granted." [34] Thus, the question for us is not whether there was *some evidence*,[35] but whether, in terms of "the actual quantum and quality of proof necessary to support liability," [36] there was *sufficient evidence* upon which a jury coud properly base a verdict for the Richardsons. They, as plaintiffs, had the burden of proving by a preponderance of the evidence that Bendectin was capable of causing birth defects of the types Carita Richardson suffered. To survive a motion for judgment n.o.v., the evidence they introduced had to be more than merely colorable; it must have been significantly probative if the jury's verdict is to stand.

III. The Evidence

The question whether Bendectin causes limb reduction defects is scientific in nature, and it is to the scientific community that the law must look for the answer. For

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[34] 477 U.S. at 249-250, 106 S.Ct. at 2511, 91 L.Ed.2d at 212 (citations omitted); see also *First Nat'l Bank* v. *Cities Serv. Co.*, 391 U.S. 253, 290, 88 S.Ct. 1575, 1593, 20 L.Ed.2d 569, 592-593 (1968) (in face of defendant's properly supported motion for summary judgment, plaintiff cannot get to the jury without "any *significant probative evidence* tending to support the complaint") (emphasis added); accord, *Merit Motors, Inc.* v. *Chrysler Corp.*, *supra* note 21, 187 U.S.App. D.C. at 14, 569 F.2d at 669.

[35] The scintilla rule has long been abolished in this circuit. *Baltimore & O. R.R.* v. *Postom*, 85 U.S.App.D.C. 207, 208, 177 F.2d 52, 54 (1949).

[36] 477 U.S. at 254, 106 S.Ct. at 2513, 91 L.Ed.2d at 215. The Court stressed that its holding did not denigrate the role of the jury. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge," whether the motion is for a summary judgment or a directed verdict. *Id.* at 255, 106 S.Ct. at 2513, 91 L.Ed.2d at 216.

this reason, expert witnesses are indispensable in a case such as this. But that is not to say that the court's hands are inexorably tied, or that it must accept uncritically any sort of opinion espoused by an expert merely because his credentials render him qualified to testify. The District Court ruled that Dr. Done's opinion lacked "a genuine basis, 'in or out of the record,'" and that his "theoretical speculations" could not sustain the Richardsons' burden of proving causation.[37] Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been met, are matters of law for the court to decide. We conclude that Dr. Done's opinion lacks an adequate basis and therefore, whether viewed alone or in conjunction with those of the other experts,[38] did not provide the "substantial probative evidence" that would require us to leave the verdict as the jury rendered it.

Federal Rule of Evidence 703 lays the foundation for our consideration of what constitutes adequate expert testimony.[39] That rule provides:

> The facts or data in the particular case upon which an expert bases an opinion or inference may

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[37] *Richardson, supra* note 6, 649 F.Supp. at 803.

[38] Despite appellant's suggestion, Brief for Appellant at 5, 40, the number of experts presented does not in itself preclude a finding that there was insufficient evidence or automatically create an issue for the jury. To create such an issue, an expert must be qualified to testify as to causation and the opinion given must have an adequate foundation. Our treatment of Dr. Done's testimony subsumes that of the other experts presented on Richardsons' behalf. See notes 40-55 *infra* and accompanying text.

[39] Other relevant rules are Fed. R. Evid. 702, which permits admission of expert testimony only if it will assist the trier of fact, and Fed. R. Evid. 403, which allows the trial court to exclude testimony if it is misleading or confusing, or if its probative value is outweighed by considerations of prejudice, confusion, or waste of time.

> be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

As we have heretofore stated, Rule 703 "was intended to broaden the acceptable bases of expert opinion, but it was not intended . . . to make summary judgment impossible whenever a party has produced an expert to support its position;" [40] rather, we emphasized, "the grounds relied on by an expert must be 'a type reasonably relied upon by experts in the particular field.'" [41] Similarly, it has been held that a scientific causation issue may be removed from the jury on a motion for a directed verdict if the evidence only "provides a 'mere possibility' yet not a 'probability' of proof." [42]

We must therefore look behind Dr. Done's ultimate conclusion that Bendictin causes birth defects and analyze the adequacy of its foundation. Dr. Done predicated his opinion upon four different factors: (1) chemical structure acitvity analysis, (2) *in vitro* (test tube) studies, (3) *in vivo* (animal) teratology studies, and (4) epidemiological studies.

In speaking of chemical structure activity analysis, Dr. Done referred to the concept that drugs with similar chemical structures may be expected to have similar properties and produce analogous effects.[43] Dr. Done noted the similarity of the chemical structures of doxylamine succinate, the antihistamine component of Ben-

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[40] *Merit Motors, Inc.* v. *Chrysler Corp., supra* note 21, 187 U.S.App.D.C. at 18, 569 F.2d at 673.

[41] *Id.* (quoting Fed. R. Evid. 703).

[42] *Marder* v. *G.D. Searle & Co.*, 630 F.Supp. 1087, 1093-1094 (D. Md. 1986), *aff'd without opinion sub nom. Wheelahan* v. *G.D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987).

[43] Trial Transcript (Tr.) 797.

dectin, and other antihistamines.[44] He then stated that "it has been known for quite awhile that antihistamines have for the most part, been capable of adversely affecting human development, including causing birth defects at least in animals. The question is not fully answered in humans yet with regard to any specific antihistamine or the group in general, but at least it does *indicate a suspicion.*"[45] As Dr. Done acknowledged, the purpose of analyzing chemical structures is to indicate what other directions a study of a substance should take; in other words, chemical structure activity analysis "gives you a clue," or "raises at least a flag to you indicating that this is a drug that you ought to and must study for teratologic effect because you may be missing something important if you don't."[46] It is thus apparent from Dr. Done's own testimony that the value of chemical structure analysis, standing alone, is extremely limited.

Dr. Done also acknowledged that *in vivo* (animal) teratology studies are similarly of but scant utility in drawing conclusions about whether a substance will cause birth defects in humans. "The fact that [a substance does so] in an animal," he conceded, "doesn't necessarily mean it will in humans, but it does mean, again, that it is likely enough to do so in humans that you have to accept the notion that it will do that unless you prove otherwise. It just increases the need to prove otherwise."[47] Dr. Done further stated that "you know that you are limited in how much you can make of this with regard to humans, but, nonetheless, it is a good place to start."[48] Here, as earlier, Dr. Done acknowledged that

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[44] Tr. 821-822.

[45] Tr. 823 (emphasis added).

[46] Tr. 798.

[47] Tr. 800.

[48] Tr. 799-800.

the *in vivo* studies served merely to raise a suspicion regarding the effect of Bendectin on humans, which by his estimate no other evidence had sufficed to wipe out.[49] Indeed, on cross-examination, Dr. Done agreed that "animal data alone would not be a sufficient bases for you to give an opinion with reasonable medical certainty that Bendectin causes birth defects in humans."[50]

The *in vitro* (test tube) experiments relied on by Dr. Done studied the effects of Bendectin components upon frog nerve fibers and the mesenchyme cells of mouse limb buds for evidence that similar or other defects might occur in humans. Again, the value of such an examination as a predictor of human teratogenicity is extremely meager, and once again we find ourselves in the realm of suspicion. Positive results from *in vitro* studies may provide a clue signaling the need for further research, but alone do not provide a satisfactory basis for opining about causation in the human context.

These three types of studies then—chemical, *in vitro*, and *in vivo*—cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence. Perhaps mindful of this, the last type of evidence considered by Dr. Done consisted of the epidemiological studies. When such studies are available and relevant, and particularly when they are numerous and span a significant period of time, they assume a very important role in determinations of questions of causation. Dr. Done himself conceded the import of this literature when he agreed on cross-examination that "in connection with the animal studies . . . because so many substances are teratogenic in animals, before

[49] Tr. 824-825.

[50] Tr. 1104.

you can make a conclusion that a substance is teratogenic in humans, you must look to the human data."[51] Dr. Done also acknowledged the necessity of a statistically significant association between the drug and its effect in human populations:

> Q. . . . Wasn't it true that you would not give an opinion as to causation without a statistically significant association in humans between the ingestion of a drug and a cause of birth defects?
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> A. That is right, not above reasonable degree of medical certainty.
>
> Q. Scientifically—
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> A. That is right.
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> Q. Putting aside medical certainty and what you are testifying here, as a scientist, you could not give an opinion as to causation without a statistically significant relationship in humans between ingestion of the drug and the malformations; isn't that correct, Doctor?
>
> A. That is fair.[52]

Dr. Done further admitted that no one who has published work on Bendectin has concluded that there is a statistically significant association between Bendectin and limb reduction defects of the type at issue in this case.[53] Only by recalculating the data was Dr. Done able to obtain what he deems a statistically significant result.[54] Moreover, the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr.

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[51] Tr. 1104.

[52] Tr. 1137.

[53] Tr. 1351.

[54] Tr. 1351.

Done has neither published his recalculations nor offered them for peer review.[55]

Since the Richardsons had the burden of proving that Bendectin causes birth defects, the law cannot tolerate a presumption of teratogenicity. That may be prudent in the medical community at the early stages of research where caution is vital and suspicion comes naturally, but it obviously is not acceptable when teratogenicity becomes an issue in a judicial tribunal.

The First Circuit expressed similar concerns in *Lynch* v. *Merrell-National Laboratories Division of Richardson-Merrell, Inc.*,[56] which involved an attempt to link Bendectin to the plaintiff's limb defects. The court noted the growing body of law recognizing the importance of epidemiologic evidence in establishing causation in cases in which no direct evidence is available.[57] The *Lynch* court found that the epidemiological studies on Bendectin concluded overwhelmingly that the drug does not cause birth defects.[58] As a result, the court ruled that Dr. Done's proffered testimony—the same sort of testimony that he

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[55] In *Perry* v. *United States*, 755 F.2d 888 (11th Cir. 1985), proof of causation was found lacking at the trial level. The epidemiological findings of a medical expert regarding a statistical connection were rejected because of the expert's methodology; it was criticized as reflecting the witness' predisposition to arrive at particular conclusions, and as devoid of any peer review of the expert's study. *Id.* at 892. The court found that the testimony of the remaining witnesses was not sufficient to demonstrate causation by a preponderance of the evidence. *Id.* at 893. "Despite appellant's protestations," the court said, "the examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine." *Id.* at 892.

[56] 830 F.2d 1190 (1st Cir. 1987), *aff'g*, 646 F.Supp. 856 (D. Mass. 1986).

[57] *Id.* at 1193-1194.

[58] *Id.* at 1194.

gave in the case at bar—was inadmissible,[59] and affirmed a grant of summary judgment for the defendant.

The Richardsons, however, direct attention to our decision in *Ferebee* v. *Chevron Chemical Co.*,[60] which involved the question whether paraquat exposure caused pulmonary fibrosis. We think reliance thereon is misplaced here. *Ferebee* is an example of "a classic battle of the experts, a battle in which the jury must decide the victor." [61] The defendant attempted to discredit the opinions of the plaintiff's experts on the ground that their views, "while not rejected by the medical community, are sufficiently novel *at this point* to be inadmissible." [62] We said:

> [A] cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, . . . products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical.[63]

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[59] Whenever expert testimony lies "at the periphery of what the scientific community considers acceptable, special care should be exercised in evaluating the reliability and probative worth of the proferred testimony under Rules 703 and 403." *In Re "Agent Orange" Prod. Liab. Litig.*, 611 F. Supp. 1223, 1242 (E.D.N.Y. 1985). In mass tort cases where there is no real understanding of the organic cause of the disease or defect, epidemiologic studies are of critical significance. *Id.* at 1239-1240. At least where epidemiological evidence was available, animal studies "are of so little probative force and are so potentially misleading as to be inadmissible." *Id.* at 1241.

[60] 237 U.S.App.D.C. 164, 736 F.2d 1529 (1984).

[61] *Id.* at 170, 736 F.2d at 1535.

[62] *Id.* (emphasis in original).

[63] *Id.* at 170-171, 736 F.2d at 1535-1536.

We noted the possibility that the case may have been the first of its type, or that the plaintiff's doctors may have been the first alert enough to recognize a causal connection between paraquat and pulmonary fibrosis.[64] We observed, too, that the fact that "science would require more evidence before conclusively considering the causation question resolved is irrelevant."[65] Thus *Ferebee* stands for the proposition that courts should be very reluctant to alter a jury's verdict when the causation issue is novel and *"stand[s] at the frontier of current medical and epidemiological inquiry."*[66] If experts are willing to testify to causation in such situations and their methodology is sound, the jury's verdict should not be disturbed.

The case before us, however, is not like *Ferebee*. Indeed, we are at the other end of the spectrum, a great distance from the "frontier of current medical and epidemiological inquiry." And far from a paucity of scientific information on the oft-asserted claim of causal relationship of Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic. Uniquely to this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their just due.

IV. Conclusion

The circumstances of the case are tragic and Carita Richardson's plight evokes the utmost sympathy. It would be foolhardy to expect members of the jury to be without compassion for the catastrophe that befell this family. That is a natural response of the human spirit, and is

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[64] *Id.* at 171, 736 F.2d at 1536.

[65] *Id.*

[66] *Id.* at 169, 736 F.2d at 1534 (emphasis added).

without legal consequence so long as it is properly controlled. But in a case such as this it not only is appropriate but indeed imperative that the court remain vigilant to ensure that neither emotion nor confusion has supplanted reason.

We arrive at our conclusions in this case fully cognizant of and particularly sensitive to the importance of the jury's role in our legal scheme. As in *Stacey* v. *Allied Stores*,[67] an age discrimination case in which a judgment n.o.v. was overturned, we are advertent to "the extraordinary judicial deference owed to jury verdicts in our system of law." [68] We realize that

> [w]e are not to tamper lightly with the considered judgment of those drawn together at one point in time to render a judgment that is representative of the good common sense of the American people. It goes without saying that few institutions are as venerable as that of trial by jury, enshrined at the Founding in the Bill of Rights and hallowed by an enormous body of English and American law that commands judges, who are of all officials the least accountable to the people, not to invade the province of judgment by the people.[69]

In *Stacey*, however, this court "discern[ed] no principled basis for concluding that [the] verdict was infected by prejudice or premised upon surmise, conjecture, or a mere scintilla of evidence." [70] We agree wholeheartedly with the court's sentiments and have no quarrel with the result. Particularly in an age discrimination case such as *Stacey*, the jury is well equipped to evaluate the evidence and use its "good common sense" to come to a

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[67] 247 U.S.App.D.C. 285, 768 F.2d 402 (1985).

[68] *Id.* at 289, 768 F.2d at 406.

[69] *Id.*

[70] *Id.* at 292, 768 F.2d at 409.

reasoned decision. The case at bar, however, is in a different category. The scientific issues are complex, the trial was lengthy, and the evidence and testimony were often difficult to understand. There was an emotional factor at play, a circumstance we are not at liberty to ignore.

It is important to also stress that the District Court's grant of judgment n.o.v. in this case did not usurp the jury's function. Whether an expert's opinion has an adequate basis, and whether without it an evidentiary burden has been carried, are issues of law falling within the province of the court. "[T]he law in its wisdom," we have observed, "has invested trial judges with the power to correct juries who base their verdicts on considerations not embodied in the evidence." [71] In this case, the District Court did exactly that and nothing more.

The judgment appealed from is accordingly

Affirmed.

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[71] *Law* v. *Virginia Stage Lines, Inc., supra* note 27, 144 U.S.App.D.C. at 119, 444 F.2d at 994.